MAY 1 7 2002

K02219

510K) Summary of Safety and Effectiveness

Date Prepared: April 12, 2002

Submitted by: Jomed Inc.
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Contact Person: Terry Schultz
Regulatory Affairs Manager
Phone Number: (858) 673-0189 Ext. 286
Fax Number: (858) 673-3837

Device Name: Jometrics SmartWire/SmartMap Pressure System

Classification Name: Catheter guide wire
Cardiovascular blood flow meter
Catheter tip pressure transducer
Vessel occlusion transducer
Patient transducer and electrical cable (including connector)

Predicate Device: WaveWire/WaveMap Pressure System, K965140

Device Description:

The Jometrics SmartWire/SmartMap Pressure System consists of the SmartWire and the SmartMap. Additionally, the SmartWire can be used with the existing WaveMap with the inclusion of the Patient Cable Model 8000.

The SmartWire is a steerable pressure monitoring guide wire used to obtain intracoronary pressure measurements before, during, and after interventional procedures. There are two lengths, 189 cm and 300 cm and the outside diameter is .014". The screw tip, core wire, proximal coil and hypotube are manufactured from stainless steel. The tip coil is composed of a platinum, iridium alloy and coated to provide lubricity. The hypotube and proximal coil are also coated to provide lubricity.

The SmartMap is designed to interface a SmartWire Pressure Wire to the auxiliary input of hemodynamic (Physio Monitor) systems. The SmartMap's power is derived from the hemodynamic system and provides in return an industry standard (AAMI BP22-2-1994) 5uV/V/mmHg output back to the hemodynamic system.

The instrument is intended to measure pressure from a pressure sensor on a guide wire in the coronary and peripheral vasculature during diagnostic and/or interventional procedures.

510(k) Summary (cont'd)

The Patient Cable Model 8000 is a preamplifier/signal condition unit designed to interface the SmartWire family of wires to an existing WaveMap Instrument. It uses intelligence to set up the circuitry designed to process the SmartWire as done in the SmartMap so that SmartWires may be used with either the SmartMap or the WaveMap.

Intended Use:

The SmartWire/SmartMap Pressure System is intended for use in the coronary and peripheral arteries to measure blood pressure during diagnostic and/or interventional procedures. The SmartWire can also be used in replacement of an angioplasty guide wire to facilitate the placement of a balloon dilation catheter, as well as other interventional devices. Blood pressure measurements are obtained to provide hemodynamic information for the diagnosis and treatment of blood vessel disease.

Device Technological Characteristics and Comparison to Predicate Device:

The SmartWire/SmartMap Pressure System uses the same fundamental scientific technology and intended use as that of the predicate device, the WaveWire/WaveMap Pressure System.

Performance Data:

Applicable testing was performed to evaluate the changes in the SmartWire/SmartMap Pressure System. The testing results were found to be comparable to those of the predicate device, the WaveWire/WaveMap Pressure System. All new materials were tested for biocompatibility according to ISO 10993.

Conclusion:

The SmartWire/SmartMap Pressure System utilizes the same fundamental scientific technology as that of the predicate device, the WaveWire/WaveMap Pressure System. The performance data and a declaration of conformity with design controls support a determination of substantial equivalence of the modified device, SmartWire/SmartMap Pressure System to the predicate device, WaveWire/WaveMap Pressure System.

K021219

Premarket Notification [510(k)] Number

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2002

Mr. Terry Schultz
Regulatory Affairs Manager
Jomed, Inc.
2870 Kilgore Rd.
Rancho Cordova, CA 95670

Re: K021219
SmartWire/SmartMap Pressure System
Regulation Number: 870.1330, 870.2870
Regulation Name: Catheter guide wire, Catheter tip pressure transducer
Regulatory Class: II (two)
Product Code: 74 DQX, DXD
Dated: April 16, 2002
Received: April 17, 2002

Dear Mr. Schultz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021219

Device Name: SmartWire/SmartMap Pressure System

Indications for Use:

The SmartWire/SmartMap Pressure System is indicated for use in all blood vessels, including coronary and peripheral arteries to measures blood pressure during diagnostic angiography and/or interventional procedures.

The intended use and indications for use of the modified device as described in its labeling have not change. The fundamental scientific technology of the modified device has not changed.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.19)

OR

Over-the Counter Use _____

Division of Cardiovascular & Respiratory Devices
510(k) Number K021219